

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

REDACTED - PUBLIC VERSION

DEFENDANTS' PROFFER OF EVIDENCE PURSUANT TO FEDERAL RULE OF EVIDENCE 103 REGARDING NON-INFRINGEMENT AND NON-ENABLEMENT RELATED TO THE CLAIM LIMITATION OF A "FRAME BEING CAPABLE FOR INTRODUCTION THROUGH AN 18 FRENCH ARTERIAL INTRODUCER"

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Medtronic Vascular, Inc.*

Dated: January 10, 2014

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES LLC AND)
EDWARDS LIFESCIENCES PVT, INC.,)
Plaintiffs,)
v.)
MEDTRONIC COREVALVE LLC,)
MEDTRONIC CV LUXEMBOURG)
S.A.R.L., MEDTRONIC VASCULAR)
GALWAY LTD., MEDTRONIC, INC.,)
AND MEDTRONIC VASCULAR, INC.,)
Defendants.)
C.A. No. 12-023-GMS
[REDACTED]

DEFENDANTS' PROFFER OF EVIDENCE PURSUANT TO FEDERAL RULE OF EVIDENCE 103 REGARDING NON-INFRINGEMENT AND NON-ENABLEMENT RELATED TO THE CLAIM LIMITATION OF A "FRAME BEING CAPABLE FOR INTRODUCTION THROUGH AN 18 FRENCH ARTERIAL INTRODUCER"

Defendants Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l., Medtronic Vascular Galway Ltd., Medtronic, Inc., and Medtronic Vascular, Inc. (collectively “Medtronic”) submit this offer of proof regarding the claim requirement “frame being capable for introduction through an 18 French arterial introducer and into a patient’s vasculature using a catheterization technique.” This proof was not presented to the jury following the Court’s ruling sustaining an objection made by plaintiffs on this subject [1/6/14 Trial Tr. 3:1-18:8; 1/7/14 Trial Tr. 326:10-328:17].¹

¹ Medtronic maintains that requiring only a naked frame to fit into the arterial introducer (even if Medtronic's product or any other product would not do this in reality) for infringement or invalidity is legally improper. This is not a reasonable application of the Court's actual claim construction, and it is erroneous as an improper *application* of the claims (as construed in the claim construction order). *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir.

NON-INFRINGEMENT

Under the Court's evidentiary ruling, Medtronic was prohibited from contending that the accused Medtronic CoreValve does not meet the claim requirement of a "frame being capable for introduction through an 18 French arterial introducer and into a patient's vasculature using a catheterization technique" because, under Medtronic's catheterization technique, the CoreValve frame and tissue components combined cannot be introduced through an 18 French (5.7 mm or less) arterial introducer. [1/6/14 Trial Tr. 3:1-18:8]. It was also prohibited from presenting the following evidence even as it relates to Medtronic's non-infringement position under the Court's construction and application of the claims as set forth at trial. *Id.*

In support of its non-infringement position, Medtronic would have offered the following evidence:

Testimony of Russ Hodge. Mr. Hodge is the senior program director for the CoreValve Program, is identified as a witness in the Pre-Trial Order (D.I. 125), and testified as a 30(b)(6) witness during fact discovery.

- Mr. Hodge would have testified at trial that the Medtronic CoreValve is not capable of being introduced into a 5.7 mm or less introducer sheath without first being fitted into a capsule which is necessary to keep the frame in its compressed state.
- Mr. Hodge would have testified at trial that, using Medtronic's catheterization technique, physicians first cool the entire valve (including both the frame and tissue), which allows the Nitinol frame to be compressed around the leaflets and skirt. The entire valve is then loaded into a capsule to keep the valve in its compressed state. [REDACTED]

2009) (reversing denial of JMOL because infringement verdict depended on an interpretation of the claim construction in the jury charge that was inconsistent with its ordinary meaning); *Cordis Corp. v. Boston Scientific Corp.*, 658 F.3d 1347, 1355-56 (Fed. Cir. 2011). Moreover, the claims should not be construed to mandate the naked frame. As a result, the Court's orders wrongly precluded Medtronic from presenting evidence relevant to the claims even as Edwards and the Court construed and applied them.

- Mr. Hodge would have testified at trial that the CoreValve frame alone is not capable of being introduced into a patient's vasculature without the valvular structure.

Testimony of Adam Podbelski. Mr. Podbelski was a senior program manager for the CoreValve Project at Medtronic. Mr. Podbelski was responsible for CoreValve product development for both the valve and the delivery system.

- At trial, Mr. Podbelski would have testified that using Medtronic's catheterization technique, which requires compression of the entire valve and not just the frame, [REDACTED].
- At trial, Mr. Podbelski would have testified, and during his deposition did testify, that [REDACTED]
- At trial, [REDACTED]

Cross-Examination Testimony of Dr. Nigel Buller. Dr. Buller is Edwards' expert on issues of non-infringement and invalidity.

- Medtronic anticipates that it would have cross-examined Dr. Buller to elicit testimony that the accused CoreValve products are not capable of being introduced into a patient's vasculature through an arterial introducer of 5.7 mm or less using Medtronic's catheterization technique because the frame is compressed and constrained using a capsule that has a diameter greater than 5.7 mm.
- Medtronic anticipates that it would have cross-examined Dr. Buller to elicit testimony that Dr. Buller never tested or identified any accused CoreValve product that was manufactured or used with a capsule to constrain the product such that the

product can be introduced into a patient's vasculature through a 5.7 mm or less arterial introducer.

Testimony of Dr. Gary Loomis. Dr. Loomis is Medtronic's expert on issues of non-infringement and invalidity.

- Dr. Loomis would have testified, consistent with his expert report, that there is no "appropriately sized capsule" that could be combined with the CoreValve so that the device is capable of introduction into a patient's vasculature through a 5.7 mm arterial introducer. [Ex. C, Rebuttal Expert Rpt. of Gary Loomis at 66-70]

NON-ENABLEMENT

Medtronic asserts that U.S. Patent No. 8,002,825 (the "825 patent") is invalid for lack of enablement. Under the Court's evidentiary ruling, Medtronic was prohibited from arguing that, for the full scope of the claim to be enabled, the specification must teach one of ordinary skill in the art to make a prosthetic valve with a frame that is compressible to an external diameter so as to be introduced through an 18 French (5.7 mm or less) arterial introducer using a catheterization technique. "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'"

MagSil Corp. v. Hitachi Global Storage Techs., 878 F.3d 1377, 1380 (Fed. Cir. 2012) (internal quotation marks omitted). It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. *Auto. Techs. Int'l, Inc. v. BMW of N. Am.*, 501 F.3d 1274, 1283 (Fed. Cir. 2012). It was also prohibited from presenting the following evidence even as it relates to Medtronic's non-enablement position under the Court's construction and application of the claims at trial.

In support of its position, Medtronic would have offered the following evidence:

Cross-Examination Testimony of Dr. Alain Cribier.

- Medtronic would have cross-examined Dr. Cribier to elicit testimony that at the

time the patent application was filed, [REDACTED]

Testimony of Dr. Gary Loomis. Dr. Loomis is Medtronic's expert on issues of non-infringement and invalidity.

- Dr. Loomis would have testified at trial, consistent with his expert report, that the '825 patent specification does not enable one of skill in the art to practice Dr. Cribier's claims with respect to making and using a prosthetic aortic valve that could be compressed to a size such that it could fit into a 5.7 mm or less arterial introducer. [See, e.g., Ex. C, Opening Expert Rpt. of Gary Loomis at pp. 52-59]

Cross-Examination Testimony of Dr. Nigel Buller. Dr. Buller is Edwards' expert on issues of non-infringement and invalidity.

- Medtronic anticipates that it would have cross-examined Dr. Buller to elicit testimony that, at the time of the invention, [REDACTED]

Trial Exhibits. In addition to the testimony cited above, Medtronic would have offered the following exhibits into evidence:

- DTX159 – [REDACTED]
- DTX0004, DTX0005, DTX0006, DTX0007, DTX0009, DTX0011, DTX0025, DTX0237 – [REDACTED]

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Dated: January 10, 2014

EXHIBITS A-L

REDACTED

CERTIFICATE OF SERVICE

I, John W. Shaw, hereby certify that on January 10, 2014, this document was served on the persons listed below in the manner indicated:

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